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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,081

06/13/2005

Kohji Fukatsu

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7590

03/23/2010

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EXAMINER

CORNET, JEAN P

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

03/23/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,081	Applicant(s) FUKATSU ET AL.	
	Examiner JEAN CORNET	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 16-23, 34, 35 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) 35, 37, 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 16, 17, 18-20, 21, 22, 23, 34 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/22/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

The amendment filed on 01/02/2010 in response to the Non-Final office Action of 10/05/2009 is acknowledged and has been entered.

Claims 13, 16-23, 34, 35, and 37-39 are pending. Since the subject matter of claim 15 is now incorporated into claim 13, claims 16-23, which depend from claim 13 and that were previously withdrawn are now rejoined. Claims 13, 16-23, 34 and new claim 39 are under current examination. Claims 35, 37-38 are remain withdrawn due to different subject matter. Claims 1-12, 14-15, 24-33 and 36 are canceled by Applicant.

Priority

Since Applicant did not submit a certified English translation of the foreign priority documents as required from the previous Office Action, no benefit has been accorded to non-English Japanese Application. Therefore the priority date still remains 11/06/2003.

Information Disclosure Statement

All reference in the IDS (02/22/2010) has been considered.

Rejections withdrawn:

Rejection Under 35 U.S.C. §112, First Paragraph

Applicant's arguments, filed on 01/05/2010 with respect to the 35 U.S.C. §112, first Paragraph have been fully considered and are persuasive. The rejection of claims 2, 3, 4, 5, 14 and 34 has

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been withdrawn because claims 1-12, 14-15 were canceled and claim 34 were amended to remove the term “prodrug”.

Claim Rejections – 35 USC 112 2nd Paragraph / 35 U.S.C. 101

Applicant’s arguments, with respect to the 35 U.S.C. §112, first Paragraph/ 35 U.S.C. 101 have been fully considered and are persuasive. The rejection of claim 36 has been withdrawn because the claim was canceled.

Claim Rejections - 35 USC § 103

Applicant’s arguments, with respect to the 35 U.S.C. §103 have been fully considered and are persuasive. The rejection of claims 1-6, 8, 9, 13, 14, 34, 36 and 38 has been withdrawn due to cancellation and amendment of the claims.

Allowable Subject Matter

The Examiner had stated in the previous Office Action that claims 15, 22 and 23 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. However upon further reconsideration of the IDS filed by Applicant on 02/22/2010, the following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

New Rejection necessitated by the IDS filed

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

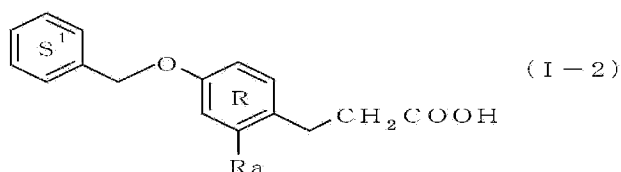
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

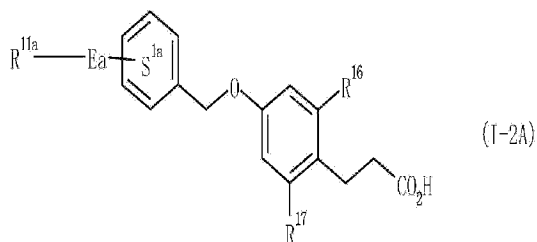
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

The instant application is drawn to a compound represented by the formula (i-2)



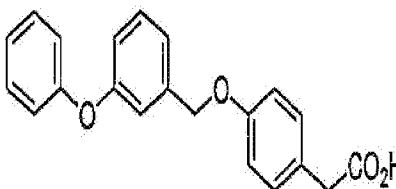
wherein ring S^1 is a benzene ring having substituent(s) having a benzene ring, wherein the substituent(s) having a benzene ring is a substituent represented by the formula: $R^{11}-E^2$ (R^{11} is a phenyl group, an indanyl group or a naphthyl group, each optionally having substituent(s), and E^2 is a bond or a spacer), and the spacer represented by E^2 is $-(CH_2)^{m^1}-W^1-(CH_2)^{m^2}-$ (m^1 and m^2 are each an integer of 0 to 3, W^1 is $-O-$, $-N(R^2)-$, $-S-$, $-CO-$ or $-CO-N(R^3)-$, and R^2 and R^3 are each a hydrogen atom or a C_{1-6} alkyl group);



Claims 13, 18-20, 22, 23, 34 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mapes et al (WO2005/009104, published on 02/03/2005, filed on 07/16/2004 and claimed benefit of 60/487,915, filed on 06/16/2003) cited in IDS reference filed on 02/22/2010.

Mapes et al teach a composition containing hepatocyte nuclear factor 4a (HFN-4a) receptor modulator compounds (abstract) such as

4-(3-phenoxybenzyloxy)phenyl acetic acid (Compound 13)



The difference between the compound of Mapes et al and the instantly claimed compound (I-2A) is that a methoxy group linking the second and the third ring contains a methyl group, R^{11a} represents a phenyl ring and Ea represents O; and R^{17} and R^{16} contain hydrogen, whereas the instant compound has an ethyl group. MPEP 2144.08.II.A.4(c) states, "... consider teachings of a preferred species within the genus. If such a species is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties."

To those skilled in the chemical art, one homologue is not an advance over another member of a homologous series. The reason for this is that one of ordinary skill, knowing the properties of one member of series, would know what properties to expect in other members. The interchange of alkyl, including methyl, and hydrogen is obvious in and of itself. *Exparte Bluestone*, 135 USPQ 199, *In re Henze*, 85 USPQ 261 (1950), *In re Wood*, 199 USPQ 137 (CCPA 1978), and *In re Lohr*, 137 USPQ 548, 549 (CCPA 1963).

One of ordinary skill would be motivated, from the exemplified embodiments in the prior art disclosure, to make modifications required to arrive at the instant invention with reasonable expectation of success for obtaining an additional compound for the same utility. The motivation would be to make additional compounds for the same quoted purpose.

Claims 16, 17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mapes et al (WO2005/009104) cited (IDS reference 02/22/2010) in view of Patini et al., (Bioisosterism: A rational Approach in Drug Design", Chem. Rev. 1998, Vol. 96, Issue 8, pages 3147-3176)

The teachings of Mapes et al have been discussed *supra*.

The structure taught by Mapes et al. does not expressly contain a halogen on the third ring as recited in claims 16, 17 and 21.

However, although not shown, the phenyl ring contains all hydrogen, whereas R^{11a} represents a phenyl ring having hydrogen and R¹⁷ is a fluoride atom and R¹⁶ is a hydrogen atom of instant compound (I-2A)

Patini et al teach that fluorine, hydroxyl, amino and methyl groups can be replaced for Hydrogen (Grimm's hydride replacement law) and the substitution will still result in no effect on biological activity.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the phenyl ring (far side to the left) taught by Mapes et al. to replace a one of the hydrogen for a fluorine to arrive at the Applicant's compound that requires an halogen on the phenyl ring labeled as R^{11a}.

One would have been motivated to make such modifications required to arrive at the instant invention with a reasonable expectation of success for obtaining an additional compound for the same quoted purpose because substituting H for F would have the same effect on biological activity as suggested by Patini et al.

Conclusion

No claims are allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 02/22/2010 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEAN CORNET whose telephone number is (571)270-7669. The examiner can normally be reached on Monday-Thursday 7.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JC/

**/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642**